No. 17-1229

In the
Supreme Court of the United States

HELSINN HEALTHCARE S.A.,
Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF

THE INTELLECTUAL PROPERTY LAW ASSOCIATION OF CHICAGO

AS *AMICUS CURIAE*

IN SUPPORT OF NEITHER PETITIONER NOR RESPONDENTS

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AAU letter	Letter, Association of American Universities et al. to attn.: Mary C. Till, Sr. Leg. Advisor, Office of Pat. Leg. Admin., Office of Dep. Comm. For Pat. Ex. Policy, October 5, 2012 ("AAU letter")
AIA	America Invents Act
AIA, Hearing	America Invents Act, *Hearing before the Subcommittee on Intellectual Property, Competition, and the Internet of the Committee on the Judiciary House of Representatives*, 112th Cong. 65 (2011)
A Patent System for the 21st Century	Stephen A. Merrill, et al, *A Patent System for the 21st Century*, National Academy of Sciences (2004)
Armitage	Robert A. Armitage
ABA-IPL	American Bar Association Section of Intellectual Property Law
AIPLA	American Intellectual Property Law Association
Harmonization Hearing	*The Patent System Harmonization Act of 1992: Joint Hearing on S. 2605 and H.R. 4978 Before the S. Comm. on the Judiciary and the Subcomm. on Intellectual Property*

	and Judicial Administration of the H. Comm. on the Judiciary, 102nd Cong. (1992)
Helsinn	*Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017)
House	House of Representatives
Individual Academics Brief	Brief of Amici Curiae 42 Intellectual Property Professors, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017)
IP	Intellectual property
IPLAC	The Intellectual Property Law Association of Chicago
Lilly	Eli Lilly & Company
Manzo	E. Manzo, *The America Invents Act: A Guide to Patent Litigation & Patent Procedure*, Thomson Reuters (Nov. 2013)
NAM	National Association of Manufacturers
Organizations	The "[n]umerous organizations, institutions, and companies [who] advocated [that] the U.S. adopt a first to file [patent] system." Sen.

	Rep. No. 111-18.
Perspectives Hearing	*Perspectives on Patents, Hearing before the Subcomm. on Intellectual Property of the Comm. on the Judiciary*, United States Senate, S. Hrg. 109-983 (2005)
USCO	United States Copyright Office
USPTO	United States Patent and Trademark Office

INTEREST OF *AMICUS CURIAE*

The Intellectual Property Law Association of Chicago ("IPLAC") submits this brief as *amicus curiae*, but in support of neither party on the ultimate merits of the case.[1, 2, 3] IPLAC has as its governing objects, *inter alia*, to aid in the development of intellectual property ("IP") laws, the administration of them, and the procedures of the U.S. Patent and Trademark Office ("USPTO"), the U.S. Copyright Office ("USCO"), and the U.S. courts and other officers and tribunals charged with

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[1] Pursuant to Supreme Court Rule 37.6, no counsel for a party authored this brief in whole or in part, no such counsel or a party made a monetary contribution intended to fund the preparation or submission of the brief, and no person other than the *amicus curiae*, its members, or its counsel, made such a monetary contribution to the preparation or submission of the brief.

[2] In addition to the required statement of footnote 1, IPLAC adds that after reasonable investigation, IPLAC believes that (a) no member of its Board or Amicus Committee who voted to prepare this brief, or any attorney in the law firm or corporation of such a member, represents a party to this litigation in this matter, (b) no representative of any party to this litigation participated in the authorship of this brief, and (c) no one other than IPLAC, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief.

[3] Pursuant to Supreme Court Rule 37.3(a), IPLAC has obtained the consent of the parties to file this amicus brief. Petitioner has filed a blanket consent letter with the Court, and Respondent has given IPLAC individual consent.

administration. IPLAC was founded in 1884 as The Patent Law Association, making it by rich history the country's oldest bar association devoted exclusively to intellectual property matters. It was dedicated on founding to "making more definite, uniform and convenient" the laws and rules of IP practice. Today, IPLAC is an association of over 1,000 members of the legal profession of the United States in good standing with interests in the laws of IP, licensed to practice in any state or the USPTO, including Chicago-local and non-local attorney members, judiciary members, and faculty members; patent agents, paralegal members, and student members. IPLAC members have their IP law interests in the areas of patents, trademarks, copyrights, trade secrets, social media, advertising, blockchain, data protection, outsourcing, privacy, and top level domains. Some members are in private and corporate practices and appear before federal courts throughout the United States, as well as the USPTO and USCO. Members represent both rights holders and other actors in roughly equal measure, and in litigation, are split roughly equally between plaintiffs and defendants. IPLAC is centered in Chicago, a principal locus and forum for the nation's authors, artists, inventors, scholarly pursuits, arts, creativity, research and development, innovation, IP creation, IP litigation, and IP awareness.

SUMMARY OF ARGUMENT

AIA §102(a)(1) has a specific structure, content, and meaning by virtue of having two "or's," an "otherwise," and an adjective "claimed" before its subject "invention." The specific meaning of AIA

§102(a)(1), after a careful analysis of the placement and meaning of these terms, is that a patent cannot issue where a claimed invention has been the subject of a patent, a printed publication, or in the alternative to patents and publications, the subject of an event that has made the claimed invention available to the public, such as a public use that makes it available to the public, an on sale that does the same, or an event that any way or manner other than an availing use or on sale makes it available to the public.

The essence of the Federal Circuit panel's *Helsinn* decision under review is its conclusion that for an invention subject to the AIA, once the existence of an inventor's terms of a sale, if any, are publicly known, and the sale is to be of the invention, then the invention is legally publicly known, even though the invention is not factually publicly known. *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1371 (Fed. Cir. 2017) , Pet. App. at 43a. Colloquially, the essence of the decision is that if the public were to know that an inventor was trying to sell an invention, and what his terms were, even if the public did not know what the invention was, the public's knowledge of the attempt to sell would itself be prior art to a later patent on the invention (one filed after a year from the knowledge).

This is a mistake as in *Pfaff v. Wells*, 525 U.S. 55 (1998), and an utterly odd conclusion for the specific structure, content, and meaning of AIA §102(a)(1), one against assessing the public availability of what §102(a)(1) focuses on, a "claimed invention," by express wording. As happened in

Pfaff, the Federal Circuit has made an on sale decision by wrongly focusing on a matter that is completely absent from the relevant text of §102. *Compare Pfaff*, 525 U.S. at 60, 66-68 (pre-AIA §102 text did not reference "substantial completion," which was the focus of the Federal Circuit decision reversed in *Pfaff*).

The numerous organizations, institutions, companies, and their representatives, driven by the 21st century needs of the country, who caused the U.S. to adopt a first-inventor-to-file patent system, accomplished the opposite of the Federal Circuit panel's decision. Their drive for patent reform and a first-inventor-to-file system began as early as the 1980s. From the beginning, they strove for simplicity, transparency, objectivity, and predictability in the patent law, and specifically within their efforts, for the curtailment and elimination of "secret prior art" from being patent-defeating prior art in their proposed first-inventor-to-file system. Their reasons were the fit of the elimination with simplicity, transparency, objectivity, and predictability. Congress passed the AIA in response to these organizations' efforts. And as early as 2007-2009, in the Reports by which the Patent Reform Acts of 2007 and 2009 introduced the AIA language of §102(a)(1)—the Acts of 2007 and 2009 were the AIA's direct predecessors—Congress informed the advocating organizations and the world at large that the coming new §102(a)(1) would have "the phrase 'available to the public' ... to emphasize the fact that [the claimed invention] must be publicly available [for it to be prior art to later attempts to patent it]." *See infra* at 9-10.

The USPTO participated in Congressional efforts to fashion and pass the Patent Reform Acts of 2007 and 2009, and the AIA, at the request of Congress, and was unquestionably aware of matters such as the two Reports' introductory explanations of the potential AIA's contents. So when, just after the passage of AIA, the USPTO informed the numerous organizations whose dedicated efforts drove the country to the AIA that the "AIA does not include the pre-AIA use of secret sales as prior art," the USPTO no doubt knew what it knew, correctly stated what it knew, and the organizations no doubt knew that the USPTO was correct in its statements. *See infra* at 14-16.

A principal representative for the organizations in patent reform, and advocate for the AIA in his own right, Robert Armitage, who spoke for the National Association of Manufacturers ("NAM"), the American Intellectual Property Law Association ("AIPLA"), the American Bar Association ("ABA"), and Eli Lilly & Company ("Lilly"), also assured the organizations *and assured Congress itself* further that "secret sales" were "not ... prior art," in authoritative explanations. *See infra* at 12-14.

Nothing in the AIA, which embodied Congress's overhaul of past patent prior art law to give the U.S. a first-inventor-to-file system, one with simplicity, transparency, objectivity, and predictability, justified the Federal Circuit panel's improper change of focus. To determine prior art, away from the matter of the public availability of a claimed invention, and instead to the matter of

whether there was public knowledge of an inventor's terms of sale, is wrong.

Regressive manufacture of worried ideas over the specifics of the text of AIA §102(a) relative to this Court's guidelines for statutory construction, mostly in the form of a parade of potential horribles for future burdens on academics and the courts to learn new law, is what has caused a dispute over the meaning of AIA §102(a)(1). But the potential horribles do not change the specific structure, content, and meaning of AIA §102(a)(1), or its history and background as known to Congress, the USPTO, dedicated and altruistic—even patriotic—organizations, and the mavens of the patent reform that provided the AIA. AIA prior art law has a sole focus on the public availability of a claimed invention itself, not an inventor's terms of sale in relation to any related invention, because of the need for consistent, universal focus on simplicity, transparency, objectivity, and predictability for patent matters in the 21st century.

The Federal Circuit panel was wrong to make it otherwise. It was wrong to misdirect itself as it did in *Pfaff*. It was wrong to snatch from Congress, the USPTO, patent reform organizations, their leaders, and the country as a whole, some of the bold, streamlining patent reform that the AIA accomplished.

STATEMENT OF FACTS

An effort of patent reform that led to the AIA, including a first-inventor-to-file patent system, began in at least one quarter as early as 1982. In

that quarter, it began with Robert Armitage. *See* Robert A. Armitage, *Reform of the Law on Interference: A New Role for an Ancient Institution in the Context of a First-to-File System*, 64 J. Pat. Off. Soc'y 663 (1982). Mr. Armitage testified before Congress in 1992 representing NAM, in part toward adoption of a first-inventor-to-file patent system and curtailment of the on sale bar to patents. *See The Patent System Harmonization Act of 1992: Joint Hearing on S. 2605 and H.R. 4978 Before the S. Comm. on the Judiciary and the Subcomm. on Intellectual Property and Judicial Administration of the H. Comm. on the Judiciary*, 102nd Cong. 186-97 (1992) ("Harmonization Hearing").

Major patent reform of the types in the AIA stalled for many early years and then, with new empirical analysis, new study, and new sharing of information, reform broke forth into a striking, new period for change. A 2004 study was released by the National Academy of Sciences ("NAS"). *See Perspectives on Patents, Hearing before the Subcommittee on Intellectual Property of the Committee on the Judiciary*, United States Senate, S. Hrg. 109-983 (2005) at 2 (new Subcommittee), 12, 24, 39, 48-49, 69, 78, 121-26, 144 (consensus) ("Perspectives Hearing"). A 2005 empirical analysis was published, with a foreword by Mr. Armitage, *id.* at 72-92, 137-145; *see also* Stephen A. Merrill, et al, *A Patent System for the 21st Century*, NAS 124-27 (2004) (consensus) ("A Patent System for the 21st Century"). A nationwide consensus rapidly developed in the patent community for the patent system to move to a first-inventor-to-file patent system. Perspectives Hearing at 30-33, 44-71. Also in 2005,

the Senate created an Intellectual Property Subcommittee of the Senate Judiciary Committee. Mr. Armitage was there as a witness to explain the new consensus.

Congress through Subcommittee Chairman Senator Hatch specifically asked the USPTO, which was present at the first hearing of the new subcommittee, to work with Congress as it fashioned patent reform legislation. *Id* at 17. Robert Armitage from the 1982 article and the Harmonization and Perspectives Hearings was already a recognized "veteran" in Congressional patent matters, *id.* at 3, a representative of NAM and Lilly in testimony, *id.* at 30-32, 44-71, a past President of the AIPLA, *id.* at 118, and co-chair of an AIPLA Special Committee on Patent Legislative Strategies, *id.* This AIPLA Special Committee developed patent reform proposals which were approved by the AIPLA Board of Directors and were explained in town hall forums across the country jointly sponsored by the Federal Trade Commission, NAS, and AIPLA. *Id.* at 117-18.

AIPLA proposed to Congress, and Lilly through Mr. Armitage endorsed, both first-inventor-to-file and "eliminating the so-called 'forfeiture' aspect of the current patent law that prevents inventors (and only the inventors) from patenting subject matter that they themselves have placed or caused to be placed into non-public commercial use or made the subject of non-public offers for sale." *Id.* at 51 n. 2. A Patent System for the 21st Century, at 124, had advocated harmonizing "rules of prior art" internationally.

Reform efforts continued over several years, in both the Senate and House. For instance, a Patent Reform Act of 2007, Senate bill 1145, introduced in a Senate Report 110-259, created a first-inventor-to-file system. This 2007 Report cited the "[n]umerous organizations, institutions, and companies" that were advocating for this system, and indicated an appearance of the USPTO in the proceedings. Senate Report 110-259 at 7 n. 24. The 2007 Report stated the Act "necessarily, modifie[d] the prior art sections of the patent law." *Id.* at 9. The 2007 Report stated as to §102 that "the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, and to emphasize that it [i.e., anything to be considered to be prior art] must be publicly available." *Id.*; E. Manzo, *The America Invents Act: A Guide to Patent Litigation & Patent Procedure*, Thomson Reuters (Nov. 2013) at 17.

The Patent Reform Act of 2009 introduced in the Senate in a Report 111-18, continued the first-inventor-to-file system of the Patent Reform Act of 2007, and again cited the "[n]umerous organizations, institutions, and companies" that were advocating for this system. 2009 Senate Report 111-18 at 3, 32, 41. The 2009 Report again stated the Act "necessarily, modifie[d] the prior art sections of the patent law." *Id.* at 6. The 2009 Report again stated as to §102 that "the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, as well as to emphasize that it [i.e., anything considered to be prior art] must be publicly available." *Id.*; *see also id.* at 32, 70; Manzo at 11.

The USPTO regularly participated in Congressional patent reform efforts, with its Director appearing and testifying multiple times. *See* 2009 Senate Report at 5 ns. 14-18.

The AIPLA compared the 2009 House and Senate bills and stated it "support[ed] amending section 102 to limit patent defeating prior art to information which is publicly accessible." AIPLA, *Summary and Comparison of H.R. 1260 and S. 515, the Patent Reform Acts of 2009*, at 1.[4]

Reform was not being limited to first-inventor-to-file and redefining prior art. *Id.* Proposals ranged across matters of derivation proceedings, inventor's oaths, assignee filing, damages, willful infringement, prior user rights, reexamination, post-grant opposition, a Patent Trial and Appeals Board, a study and report on reexamination, publication of patent applications, third party submissions of prior art, venue for patent infringement cases, interlocutory appeals, USPTO fee setting authority and a variety of additional matters to a total of thirty-one distinct potential areas of reform. *Id.*

A 2011 Senate amendment made the act in the Senate at that time the "America Invents Act." *See* J. Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 445 (2012). A surprising and intense last-minute debate over first-inventor-to-file occurred. *Id.*

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[4] *See* http://www.aipla.org/Advocacy%20Shared%20Documents/PatentReformLegComparisonChart-050509.pdf

at 453-461. The Senate bill passed. The House considered the America Invents Act as H.R. 1249 in 2011. *See America Invents Act, Hearing before the Subcomm. on Intellectual Property, Competition, and the Internet of the Comm. on the Judiciary House of Representatives*, 112th Cong. 65 (2011) ("AIA Hearing"); *see also* Matal, 21 Fed. Cir. B.J. 461-464. The AIA in this hearing had the proposed §102 of the Patent Reform Acts of 2007 and 2009 in the Senate, and the §102 the AIA now has. AIA, Hearing at 4. The USPTO called first-inventor-to-file essential. *Id.* at 44. A witness reiterated that the AIA was to have "changes that bring objectivity to the determination of what information can be used to assess the patentability of an invention – patents, printed publications, or other publicly known information." *Id.* at 71. The House Report itself was confirming, that "[t]he Act simplifies how prior art is determined, provides more certainty, and reduces the cost associated with filing and litigating patents." The House passed the AIA, and then the Senate passed it as well. Matal, 21 Fed. Cir. B.J. at 464-466.

Reviewing the AIA the day after it passed the House and Senate, and well before its Presidential signing, Senator Leahy advised all involved that §102(a)(1) "was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art." He stated that patent-defeating prior art must meet the "the public accessibility standard that is well-settled in current law, especially case law of the Federal Circuit." 157 Cong.

Rec. S1496-S1497 (daily ed., March 9, 2011), (Statement of Sen. Leahy).

Also reviewing the changes of the AIA, Mr. Matal, Judiciary Committee Counsel to Senator Kyl, stated that "The new §102 ... sweeps away a large body of patent law. All the 'loss of right to patent' provisions of pre-AIA §102 have been repealed. ... The new subsection (a)(1): (1) incorporates pre-AIA §102(b)'s inclusion of the patent owner's own activities, including public commercialization of the invention ... In light of the AIA's repeal of all 'loss of right to patent' provisions based on secret activities from §102, those words have been removed from the title of §102. ..." Matal, 21 Fed. Cir. B.J. 450. He added as to §102 (a)(1) that it "allows a patent to issue unless there has been a 'public disclosure of prior art.' This prior art can come in any form that makes the invention publicly accessible." *Id.* at 451.

Mr. Armitage, patent veteran, witness in multiple appearances, past advocate for major patent reform and what became the AIA, for NAM, AIPLA, and Lilly, was by the time being referenced also Chair of the ABA Section of Intellectual Property Law ("ABA-IPL"). He reviewed AIA's changes, stating that with the AIA, "Congress completed a statutory patent revolution." R. Armitage, *Understanding the America Invents Act and its Implications for Patenting*, 40 AIPLA J. 1, 8 (2012) . He stated that inventions were patentable if the claimed invention was sufficiently different from "the prior art, which consists of—1) disclosures made available to the public (*i.e.*, subject matter publicly accessible)." *Id.* at 22 (item 2 not relevant)). He

continued, that understanding that prior art had to be publicly accessible was critical to understanding what the AIA created in a new patent system:

> Thus, by far, the provisions of the AIA that are of the utmost importance to realizing the benefits contemplated by the reforms are premised on the successful implementation of the new statutory definition for 'prior art.' Either this new definition will successfully translate into prior public disclosures, ... or it would be difficult to make sense of what Congress has done in the aggregate for patent law ...

Id. at 23.

As if that were not definitive enough on the subject, he continued that "a 'disclosure' is now the sole route by which subject matter qualifies as prior art." *Id.* at 29. He persuasively critiqued past "on sale" law as having a "bizarre defect" in forcing forfeiture of patent rights over inventor activities that were in secret. *Id.* at 42-43. He thoroughly explained that in the AIA, Congress "erase[d] each of the ancient 'loss of right to patent' provisions from pre-AIA §102." *Id.* at 45, also 50-51, 52. This was a "process of conscious subtraction," he said. *Id.* at 46. Indeed, he observed:

> [the] terms "in public use or on sale" have been further modified

> and qualified by a new phrase that reads in its entirety: "in public use, on sale, or otherwise available to the public." Congress employed this mechanism to impose an overarching requirement for availability to the public in order for a prior disclosure to constitute prior art. ... can the new language somehow read to allow secret uses or secret offers for sale or other secret or private acts, unavailable to the public, to impact patentability ...? There is abundant ground for confidence that the clarity of the new language will not be negated by the courts ... The overarching requirement for a disclosure to be "available to the public" has been placed into new §102(a)(1) in a manner making it virtually impossible to read it other than as an express repudiation of the Metallizing Engineering doctrine.[5]

Id. at 53-4.

Mr. Armitage drove his point home that secret on sale activity is not prior art under the AIA with repeated, effective blows that defy contradiction. In

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[5] *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946)

addition to the above, *see, e.g., id.* at 54-60 and especially n. 206 regarding sale activities and forfeiture.

Proved in the briefs of others, the USPTO adopted the positions of Congress, its members, and the advocating organizations and their representatives, most notably the spokesman and historian, Mr. Armitage. *See* references above; *see also ABA-IPL letter to David Kappos, Under Secretary of Commerce for Intellectual Property and Director of the USPTO*, November 17, 2011, at 2 on §102(a)(1).[6] Moreover, Mr. Armitage reported back to Congress about the USPTO implementation of the AIA. *See Statement of Robert A. Armitage, Senior Vice President and General Counsel, Eli Lilly & Company, Indianapolis, Indiana, before the United States House of Representatives Committee on the Judiciary on "Implementation of the Leahy-Smith America Invents Act,"* May 16, 2012. Mr. Armitage testified, again repeatedly, with reinforcement in the Matal and Leahy analyses referenced above, and in his own analyses, that the AIA ended forfeiture provisions in pre-AIA law, required public disclosure of the subject matter of patent claims for inventor actions before patent applications to cause prior art, and did so by "consensus position of the U.S. patent user community." *Id.* at 4-14 (consensus on 6). He urged that Congress "speak ... until no doubt exists as to the words it placed in the statute and the import and intent of those words." *Id.* at 14. He

[6] *See* https://www.uspto.gov/sites/default/files/patents/law/comments/x_aia-a_aba_20111117.pdf.

advocated that Congress have the USPTO adopt the positions of Congress—and the USPTO did.

Indeed, first the USPTO requested comments. In response, an association of 59 preeminent research universities, a council representing the presidents of 1,800 accredited universities, and four other associations representing similarly large and prestigious academic groups, stated that they had collaborated throughout the enactment of the AIA, knew there was an extensive body of pre-AIA case law, and yet that "non-public offers for sale should not be considered prior art precisely because they are not public." *Letter, Association of American Universities et al. to attn.: Mary C. Till, Sr. Leg. Advisor, Office of Pat. Leg. Admin., Office of Dep. Comm. For Pat. Ex. Policy*, October 5, 2012 ("AAU letter").[7]

Then, in educating the public to the AIA, the USPTO went out in "Road Shows," and informed everyone paying attention that the "AIA does not include the pre-AIA use of secret sales as prior art."[8] The patent user community has as a result, since these events, acted in reliance on the AIA eliminating secret sales as prior art.

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[7] *See* https://www.uspto.gov/patent/laws-and-regulationscomments-public/comments-examination-guidelines-implementing-first

[8] *See* https://www.uspto.gov/sites/default/files/aia_implementation/fitf_live_overview_training_slides-march2013.pdf at 13 slide 25.

Meanwhile, for patents not subject to the AIA, most pre-AIA law continued in effect.

ARGUMENT

I. AIA §102(a)(1) has a specific structure and content: two "or's," an "otherwise," and a "'claimed' invention" as its subject.

The starting point for this Court's efforts in this case is the text of AIA §102(a)(1). The text has a specific structure and content. It—unusually—has two "or's." It has an "otherwise." It has the adjective "claimed" before the word "invention" in its subject. Italicized at the referenced words, this is its structure and content:

> [A person shall be entitled to a patent unless -]
>
> (1) the *claimed* invention was patented, described in a printed publication, *or* in public use, on sale, *or otherwise* available to the public before the effective filing date of the claimed invention[.]

II. The specific structure and content of AIA §102(a)(1), *i.e.*, its two "or's," "otherwise," and "'claimed' invention," give it a specific meaning.

The cited two "or's," "otherwise," and "'claimed' invention" give AIA §102(a)(1) a specific meaning. The two "or's" start the point. The first "or" links the terms "patented" and "described in a printed publication" with each other and with the terms "in public use," "on sale," and "available to the public." The first "or" links to give AIA §102(a)(1) a first

alternative term "patented," a second alternative term "described in a printed publication," and a third alternative, a group of terms "in public use," "on sale," and "available to the public." The first term, second term, and group are themselves a group. The "group" "in public use," etc., is a subgroup.

The second "or" links the three alternative terms in the subgroup: "in public use," "on sale," and "available to the public."

With the effect of the two "or's" seen, the effect of the "otherwise" can be seen. The terms "in public use," "on sale," and "available to the public" are alternatives in a subgroup separated from the preceding two terms that are in parallel to the subgroup, *i.e.*, the terms "patented," and "described in a printed publication." The "otherwise," in the subgroup, not in position superior to being in the subgroup—not placed after the first "or"—further joins the terms "in public use," "on sale," and "available to the public," and does not affect the terms "patented" and "described in a printed publication." The "otherwise" has an effect on the terms of the group "in public use," "on sale," and "available to the public," that according to precedent, arises from two primary possible meanings for "otherwise:" "to the contrary," or "in a different way or manner." *See, e.g.*, *Marx v. General Revenue Corp.*, 568 U.S. 371 (2013)(compare the majority use of "to the contrary" with the minority use of "in a different way or manner").

The word "otherwise" in §102(a)(1) is to be understood to mean "in a different way or manner"

for one central reason. The terms "in public use" and "on sale," to their primary purpose, are terms consistent with pre-AIA case law—unless modified in §102(a)(1), which they are, as will be seen—*i.e.*, they are terms that could reflect events that made inventions "available to the public." "Public use," pre-AIA, could in some cases be private, but for the most part public uses were public. "On sale" could be the same. Thus, reading "otherwise" to mean "to the contrary" makes no sense. Reading it so would take the position that in no past cases have the terms "in public use" and "on sale" related to events that made inventions "available to the public." But in many and most past cases they had so related.

Since the word "otherwise" cannot sensibly mean "to the contrary," the word "otherwise" means "in a different way or manner." With "otherwise" interpreted, the subgroup of terms in §102(a)(1) reads "in public use, on sale, or in a different way or manner available to the public." The modification "otherwise" makes "in public use," "on sale," and "available to the public" three alternatives in their subgroup *of a kind* with each other and with only a different way or manner to them: it makes them alternatives of a kind in that in some way or manner they are events that make an invention "available to the public."

The adjective "claimed" in the subject "claimed invention" completes the specific structure and content of §102(a)(1) for this case's needs. It is a "claimed" invention and not some other invention that is the subject. For example, a claimed process, and not a product of the process, is the subject of

§102(a)(1). Since the patent to be issued on the "claimed invention" does not exist at the time that is the subject of §102(a)(1), neither does the claim to the invention; attention is required to a future patent's claims, not some loose thought of what was "the invention" in any aspect, claimed or unclaimed. For example, attention is required to a claimed process, not the product of the process, which might but for the term "'claimed' invention" have been considered an aspect of the subject invention. Attention is required to the claimed invention, not an accompanying or "companion" invention, especially not one unclaimed.

The specific subject of AIA §102(a)(1), as can be seen after this analysis, is whether a claimed invention—not any invention, not a companion invention, a product of invention, or an aspect of invention—has been the subject of a patent, a printed publication, or in the alternative to patents and publications, the subject of any way or manner of the making of public availability, such as a public use that makes the claimed invention available to the public, an on sale that makes the claimed invention available to the public, or any other way or manner that makes the claimed invention available to the public. To interpret §102(a)(1) differently would require that its specific structure and content be ignored.

III. The legislative history thoroughly and consistently affirms the structure, content, and meaning of AIA §102(a)(1).

There can be no doubt that "[n]umerous organizations, institutions, and companies ...

advocated [that] the U.S. adopt a first to file [patent] system." *See infra* Statement of Facts. The AIA exists because all these organizations, institutions and companies ("organizations") caused the AIA to come into existence. NAS issued a compelling report, the organizations developed consensus, and all involved acted on the consensus. The organizations' altruistic and dedicated advocacy for patent reform and a first-inventor-to-file system began as early as the 1980s, and those involved, specifically including and not limited to Mr. Armitage, representative of NAM, AIPLA, ABA-IPL, and Lilly, and representative of the consensus of the whole patent user community, advocated from the beginning expressly for a patent system for this 21st century, not one of the immediately past century, including the curtailment and elimination of "secret prior art" from being prior art in their proposed first-inventor-to-file system. As in the Statement of Facts, Congress passed the AIA in direct response to these organizations' multi-year and multi-decade efforts on behalf of the country, one that competes in a world of global technological innovation of tens of countries, including, prominently, China, Japan, Korea, other Asian countries, many European countries, and American countries, not one of U.S. innovation competing with British or perhaps British and German innovation alone.

As early as 2007, the 2007 Report 110-259, submitted by Senator Leahy, made an "alpha" statement that anything to be considered prior art "must be publicly available." 2007 Rep. at 9; Manzo at 17.

As early as 2009, in the 2009 Report, also submitted by Senator Leahy, at 6, the alpha statement was repeated.

In 2011, Senator Leahy added an "omega" statement to the alpha 2007 and 2009 Senate Report statements—well before the signing by the President, and thus within the limits of the legislative history, a history that could end only as of Presidential signature—that §102(a)(1) "was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art." 157 Cong. Rec. S1496-S1497. (daily ed., March 9, 2011), (Statement of Sen. Leahy).

As reflected in the Statement of Facts, the legislative record and public history between and after the alpha and omega statements are replete with utterly consistent statements of the many participants in the legislative process that secret sale prior art is eliminated by the AIA. While in 2011 there was surprise contentiousness over the first-inventor-to-file system, never was there anything undercutting or curtailment of the scope of the on sale bar (along with its companion expansion to worldwide coverage) that was present in the Patent Reform Acts of 2007 and 2009 and their Reports.

The USPTO participated in Congressional efforts to fashion and pass the AIA and Patent Reform Acts of 2007 and 2009, at the request of Congress in 2005, and was perfectly aware of matters such as the alpha, omega, and all the

confirmatory explanations of the potential laws' contents as to the necessity of public accessibility of claimed inventions for them to be prior art. So when, just after the passage of AIA, the USPTO informed the numerous organizations that the "AIA does not include the pre-AIA use of secret sales as prior art," the USPTO no doubt knew what it knew, correctly stated what it knew, and the organizations no doubt believed the USPTO, because they knew that truth too.[9]

A principal representative for the organizations in patent reform, and unquestionably the single prime reporter of the patent reform that resulted in the AIA across all the years of efforts to pass it, Robert Armitage of NAM, AIPLA, ABA-IPL, and Lilly, also assured the organizations *and assured Congress itself* further that "secret sales" were "not ... prior art" in authoritative explanations. *E.g.*, R. Armitage, 40 AIPLA Q. J. 1 (2012) ; *Statement of Robert A. Armitage*, May 16, 2012 at 2 ("Congress took bold steps ... The 'loss of right to patent' provisions were all repealed.").

IV. The "Federico of the AIA" thoroughly and consistently affirmed the structure, content, meaning, and legislative history of AIA §102(a)(1).

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[9] *See* https://www.uspto.gov/sites/default/files/aia_implementation/fitf_live_overview_training_slides-march2013.pdf at 13 slide 25.

In interpreting the *pre*-AIA patent law, *i.e.*, the 1952 Patent Act, the courts and patent user community of the late 20th century frequently could consult no better a resource on the meaning of the law than the writings and expressed thoughts of P.J. Federico, the USPTO historian and a principal draftsman of the 1952 Act.[10] For example, this Court quoted Mr. Federico's testimony before Congress in interpreting the law. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 n. 6 (1980).

This Court in this case on the interpretation of the AIA could do no better for the meaning of the AIA than turn to the writings of Mr. Armitage, fairly to be called the "Federico of the AIA." Indeed, if anything, Mr. Armitage is many things more than what Mr. Federico was, in being a readily identifiable single human representative of many AIA-critical organizations and the prime reporter over all the years of the change to a United States patent system for this 21st Century, the AIA.

Mr. Armitage began listening, speaking, and testifying to Congress about a first-inventor-to-file system, that the AIA now effects, decades earlier than the passage of the AIA. He listened to and spoke for NAM, AIPLA, ABA-IPL, Lilly—and indeed Congress itself—in explaining the need, benefits, and particulars of the new law. He was one of only 4 people acknowledged and thanked for being "key members of the 21st Century Coalition for Patent

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[10] *See* https://en.wikipedia.org/wiki/Pasquale_Joseph_Federico.

Reform, who have devoted countless hours" to the AIA, who "stuck with it through thick and thin," "formed a 'kitchen cabinet' ... indispensable to the ... drafting of this bill," and had "a key role in the creation of the America Invents Act." Congressional Record March 8, 2011 S1394. Some in the patent user community consider him at least "one of the principal architects of the AIA," N. Pierce, *Inventorship, Double Patenting, and the America Invents Act*, 30:2 Berk. Tech. J. 1613, 1626 (2015). But most like Federico the historian, he was the prime reporter on the passage of the AIA from early days through and beyond its passage.

Mr. Armitage was awarded entry into the IP Hall of Fame for his stature in patent law and being what he was as to the AIA, "a tireless campaigner for US patent reform."[11] The Chair of the ABA IPL Section who followed Mr. Armitage as Chair awarded him the first page of the bill that became the AIA, framed, in additional recognition of his efforts. As in the Statement of Facts, Mr. Armitage wrote profusely, directly, consistently, and informed by full knowledge of Congressional statutory words and intentions, that the AIA was not to have decisions made about it such as that made by the Federal Circuit panel, in response to the advocacy of academics or otherwise.[12] His views are corroborated

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[11] IP Hall of Fame, Inductees, https://www.iphalloffame.com/home/inductees/ (last visited Aug. 27, 2018).

[12] None of the other three people who were key members and had a key role in the creation of the AIA have written as he has.

by authoritative others. And the academics who will be addressed next were not there; they did not dwell in the decades and with the organizations and the Congresses of the law's creation over the many, many years.[13] Mr. Armitage did.

V. Debate over AIA §102(a)(1) is a regressive, after-the-fact, academic manufacture

What has happened to the AIA to cause the Federal Circuit panel's *Helsinn* decision is not a dispute over the content of AIA §102(a)(1), the stated events of the legislative history, especially not a consensus resulting from a NAS empirical study, or the status or pronouncements of all involved including Mr. Armitage. It is instead a regressive, after-the-fact, small-group-academic manufacture of a dispute over the meaning of AIA §102(a)(1), *compare, e.g.*, Brief of Amici Curiae 42 Intellectual Property Professors, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017) ("Individual Academics Brief") with the AAU letter from thousands of prestigious academic institutions.[14] The ponderings and wanderings of

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[13] Prof. Lemley testified once limited to bad patents, injunctions, damages, and venue. Mr. Armitage rightly humbly credits the NAS 2004 report that provided patent consensus as the motive force behind the AIA.

[14] The academic brief admits the academics "sign in their individual capacity." Individual Academics Brief at *ii*. Some contradict their institutions, who signed on to the AAU letter, *supra* at 16.

this small-group "no-change-to-the-on-sale-bar" side of this manufactured dispute, however, do not change the structure, content, meaning, history, purpose, background, or "revolution" of the AIA, as known to Congress, the USPTO, advocating and attentive organizations, and the mavens of the patent reform, especially those who were in-the-trenches, and most especially the most trustworthy spokesman and historian, Mr. Armitage.

Consistent with everything that everyone but one party, Johnny-come-latelies, and the Federal Circuit panel have written, AIA prior art law has a sole focus on the public availability of a claimed invention itself, not an inventor's on sale actions or terms of sale in relation to some loosely considered invention. AIA §102(a)(1) states the focus is whether "*the claimed invention* was patented, described in a printed publication, *or* in public use, on sale, *or* ***otherwise available to the public*** ..." (emphasis added). The subject of inquiry is always "the claimed invention." It is never the inventors' actions or terms of sale. As Federico of the AIA Mr. Armitage stated to Congress itself, it is at best "difficult to understand how any holistic reading of the new definition of prior art under §102(b) could lead to a conclusion" consistent with that of the few academics. Armitage, 40 AIPLA Q.J. at 8-9. As said by Manzo at 7-10, *see* also 19-20, "availability to the public is the touchstone for determining whether something is prior art, and secret uses or sales are not intended by Congress to form prior art for patents granted under the new FITF [first-inventor-to-file] system."

Nothing in the AIA—which (a) embodied Congress's "bold steps" in overhaul of past patent prior art law to give the U.S. a first-inventor-to-file system, (b) revised 35 U.S.C. §102(a)(1) to have the described specific structure, content, and meaning, and most specifically to have the phrase "available to the public" to "emphasize that" anything to be prior art "must be publicly available," as in the 2007 and 2009 Reports at 6 and 6, respectively, *see* Manzo at 17, and (c) "was drafted ... *to do away with* precedent under current law that private offers for sale ... may be deemed patent-defeating prior art," Cong. Rec. S1496 (emphasis added)—justified the Federal Circuit's improper change of focus from public availability of an invention to public knowledge of an inventor's actions

VI. The essence of the Federal Circuit panel's *Helsinn* decision under review is its conclusion to the opposite of AIA §102(a)(1).

The essence of the Federal Circuit panel's *Helsinn* decision under review is its conclusion that for an invention that is subject to the AIA, if the existence of the terms of a sale were to be publicly known, the sale were to be by an inventor, and the sale were to be of the invention, then the invention is legally publicly known, even if the invention is not factually publicly known:

> [The court] conclude[s] that, after the AIA, if the existence of [a] sale is public, the details of the invention need not be publicly disclosed in the terms of sale

> [for] the ... AIA on-sale bar [of AIA 35 U.S.C. §102(a)(1) to] apply."

Helsinn at 27, Pet. App. A at 43a.

As in the Summary above, stated differently, this is a conclusion that if the terms of sale of an on sale activity of a claimed inventor does not make an invention available to the public, such that the public cannot make or use that invention just by knowing the terms of sale, nevertheless, public knowledge of the terms of sale makes the invention available to the public as a matter of AIA prior art law. This conclusion therefore renders the on sale activity potentially invalidating prior art to a later-filed AIA patent on the invention, if the fact of the existence of the on sale activity by itself were to have been available to the public at the time of the on sale activity.

The Federal Circuit panel's decision is contrary to AIA §102(a)(1).

VII. The Federal Circuit panel's conclusion is a *Pfaff*-like mistake. It is a dramatically odd and wrong interpretation for the AIA based not only on the specific structure, content, and meaning of AIA §102(a)(1), but also the consistent statements from Congress, all those involved in the passage of the AIA, and the "Federico of the AIA," from 2007 to the present, that are contrary to the interpretation.

The Federal Circuit panel's *Helsinn* interpretation is a dramatically odd interpretation of AIA §102(a)(1).

This is no different in kind than the mistake the Federal Circuit made in *Pfaff*. As happened in *Pfaff*, the Federal Circuit has made an on sale decision by wrongly focusing on a matter that is completely absent from the relevant text of §102. In *Pfaff*, *see* at 66-68, the pre-AIA §102 text did not reference "substantial completion," but that was the focus of the Federal Circuit decision, that this Court reversed. Here, the text of AIA §102 does not reference "terms of sale," but terms of sale are the focus of the Federal Circuit's decision. Just as in *Pfaff*, the decision here should be reversed.

The Federal Circuit panel's interpretation of the AIA is completely at odds with its specific structure, content, meaning, history, purpose, background, and revolutionary nature. The Federal Circuit panel was wrong to make the AIA otherwise. It was wrong to snatch from Congress, the USPTO, patent reforming organizations, and their representatives, especially those present in the moment, some of the bold patent reform that the AIA accomplished.

VIII. Small-group academic arguments against the right interpretation of AIA §102(a)(1) are flawed.

The small-group academic arguments against the right interpretation of the AIA in this case are flawed.

Starting an analysis anywhere but the words of §102(a)(1), as the individual academics do, Individual Academics Brief at 2-5, is wrong. As well, generic rules of statutory interpretation must yield to the specific case where structure, content, meaning, import, intention—are openly known. A parade of potential horribles for future burdens on academics and the courts to learn new law does not change AIA §102(a)(1).

The "revolution" that is AIA must be recognized. The academics and Federal Circuit panel also rely on lack of reference to multiple specific past cases about loss of patent rights due to secret on sale activity, but the reliance must be dismissed. Congress was rewriting essentially *all* of patent law. It was rewriting all of prior art law. It was removing all of forfeiture-of-right-to-patent provisions from the law. Congress was handling and frying so many big fish in the passage of the AIA, with thirty-one distinct areas of reform under consideration, that it can hardly be criticized for not speaking about each scale, each precedent, it was de-scaling from the law. That is especially true where it spoke to the de-scaling in sweeping terms, of sweeping away centuries of patent law, and *by speaking about the categories being de-scaled,* such as that §102(a)(1) "was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art." 157 Cong. Rec. S1496. Congress left to the prime movers of the organizations who drove the reform effort, the USPTO and historians, including

especially Mr. Armitage, the job of explaining the details of the de-scaling. They did, unwaveringly.

Moreover, Congress can hardly be blamed for not giving a chapter and verse statement of what it found wrong with the past law, because it was *not* gutting the law of the past, that is, the law that was *still to exist and to apply to all ongoing pre-AIA patents and their examination and dispute resolution in litigation and otherwise.* Instead, it was in fact leaving most of the existing law untouched, and in effect, for all those pre-AIA patents that continue to exist in great numbers to this day and will exist in large numbers for about the next 20 years, or more. For AIA patents, Congress was replacing the past law essentially *in toto*, true, but for all pre-AIA patents and for a significant period of the future, it was also leaving the past law intact *in toto* for all pre-AIA patents. That notably explains, for example, why Congress did not reference in its reports the Court's recent on sale bar case, *Pfaff*, which has a two-part test for the on sale bar, neither part of which is secrecy or public availability of the claimed invention. *Pfaff* was to remain—does remain—good law, not being overturned. It is good law, for pre-AIA patents—but it must now fit within AIA §102(a)(1) with its two-part test applied to on sale activities that make a claimed invention publicly accessible, and not to on sale activities that do not make a claimed invention so accessible.

Congress passed the AIA with inventor forfeiture-of-right-to-patent provisions removed from the law for many good and valid reasons, explained eloquently in the briefs of others, such as the Brief

for *Amicus Curiae* Congressman Lamar Smith in Support of Petitioner in this case, March 27, 2018, counsel of record—Robert A. Armitage. These include "transparency, objectivity, predictability, and—above all—simplicity." *Id.* at 1. Eliminating forfeiture-of-right-to-patent provisions is critical to transparency, objectivity, predictability, and simplicity because everyone in the patent system at all stages of activity in relation to patents can, in the new patent system with this elimination, assess patent validity much more predictably, without concern that secret events could upset assessments, such as those events to be revealed usually in the future only after expensive litigation-discovery fights. Retaining forfeiture provisions greatly complicates all of the patent system and patent practice, as it did in the past, and as wanted to be eliminated in the future.

"[N]o reading of the new statute [the AIA] can contort the words ... to fit therein [an] on sale bar [that is a forfeiture-of-right-to-patent provision as in the *Helsinn* panel decision]." *Id.* at 5. That is correct, as a matter of staying true to transparency, objectivity, predictability, and simplicity, as Congress, the USPTO, and all advocating organizations and persons for the AIA wanted and want.

As in Armitage, 40 AIPLA Q. J. at 8, quoted above, "Congress completed a statutory patent revolution":

> [The] terms "in public use or on sale" [were] modified and qualified by a new phrase that reads in its entirety: "in public use, on sale, or

> otherwise available to the public." Congress employed this mechanism to impose an overarching requirement for availability to the public in order for a prior disclosure to constitute prior art. ... The overarching requirement for a disclosure to be "available to the public" has been placed into new §102(a)(1) in a manner making it virtually impossible to read it other than as an express repudiation of the Metallizing Engineering doctrine.

The Court should read the new phrase "in public use, on sale, or otherwise available to the public" as "impos[ing] an overarching requirement for availability to the public," and not do what is "virtually impossible." The phrase was "placed into §102(a)(1) in a manner making it virtually impossible to read it" other than imposing the overarching requirement. The change wrought by AIA §102(a)(1) is not anything like an "elephant" placed in a "mouse hole," either. The change is the open capture and elimination of a pesky mouse, secret prior art, with a big mouse trap, namely the express structure, content, and meaning of AIA §102(a)(1).

IX. The Court should not concern itself that some future inventors might take benefit of both trade secrecy and later patenting; the matter is already handled.

Finally, this Court should not concern itself that a few or more future inventors under the AIA might take the benefits of both trade secrecy and later patenting. The world of competing inventions and inventors in the 21st Century is *sui generis* from the past, and now global. The world of use and sale prior art is also *sui generis* from the past, and again global. As well as patenting and publications, the world of use and sale prior art is now universal among all but few of the world's billions of humans. And the drive to be the first inventor to file anywhere in the world and thereby first under the AIA reaches to all corners, wherever innovation is found, because, to coin a phrase for the world's harmonized patent systems, "to the first filer go the spoils." Worldwide impetus to compete and be first takes more than full care of those who would think to game the system, at a much higher level than a narrow on sale forfeiture aspect such as U.S. patent law had pre-AIA. Indeed, the patent community, Congress, and the AIA, especially the AIA, *have* already taken care of gamers.

CONCLUSION

The Federal Circuit panel should be reversed, to the benefit of a revolutionary patent system for this revolutionary century.

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